

REMARKS

Claims 1-31 are pending in the application. Claims 4, 6, 7, 13, and 20 have been cancelled from the application. Therefore, claims 1-3, 5, 8-12, 14-19, and 21-31 are at issue.

Claims 1-3, 5, 8-12, 19-21, 25, 28, 29, and 30 have been amended to conform the scope of the claims to examiner's Group I, which the examiner has examined in its entirety (Office Action, page 4, first paragraph). Claim 7 has been withdrawn from consideration and cancelled without prejudice to filing a continuing application directed to the subject matter of claim 7. Claims 4, 6, 13, and 20 have been cancelled to conform to the elected invention, as opposed to reasons of patentability, without prejudice to filing continuing applications directed to the subject matter of these claims.

The examiner stated that claims 19-25 and 28-31 are allowable if amended to conform to examiner's Group I and overcome the rejections of 35 U.S.C. §112, second paragraph. In view of the amendments to the claims, and for the reasons set forth below, it is submitted that these claims are in a condition for allowance.

First, the claims have been amended to conform in scope to the examined subject matter.

Second, claim 1 and claims depending therefrom stand rejected under 35 U.S.C. §112, second paragraph, for failing to recite a "therapeutically" effective amount. Claim 1 has been amended as suggested by

the examiner, and, accordingly, this rejection under 35 U.S.C. §112, second paragraph, has been overcome.

Third, claims 1, 8, and 19 stand rejected under 35 U.S.C. §112, second paragraph, for failing to recite "or" prior to the term "prodrug." In view of the amendment to claims 1, 8, and 19, it is submitted that this rejection has been overcome and should be withdrawn.

Fourth, claims 1, 8, 19, and 28-30 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite with respect to the variable W and substituents on W. It must be noted that the definition of W in claims 1, 8, 19, and 30 is clear, i.e., W is pyrazinyl. Amended claims 28 and 29 recite compounds wherein W is pyrazinyl.

With respect to optional substituents on W, applicants respectfully traverse the rejection. In particular, applicants respectfully submit that it is not necessary to restrict the scope of the claims by specifying the ring size, number of heteroatoms, or connecting point to "the main core" in order to satisfy 35 U.S.C. §112, second paragraph. As set forth in the M.P.E.P. at §2171, the purpose of the 35 U.S.C. §112, second paragraph, requirement to "particularly point out and distinctly claim" under is to define the metes and bounds of the subject matter that applicants seek to protect. Applicants respectfully submit that a person skilled in the art can readily ascertain whether a given compound falls within the generic formulae as presently claimed. As a nonlimiting example, the terms the examiner apparently objects to, e.g., "heterocyclo-

alkyl," "heteroaryl," and "aryl," have well-established meanings in the art. Moreover, each of these terms is described in the specification, and the specification also provides nonlimiting examples. For example, a nonlimiting description of "heterocycloalkyl" can be found in the specification at page 30, line 23 through page 31, line 2. For a description of "alkylene," see page 31, lines 9-15 of the specification. For a description of "aryl" and "heteroaryl," see page 31, line 19 through page 32, line 23 of the specification.

The examiner also is reminded that claim breadth does not equate to indefiniteness (see M.P.E.P. §2174.04). Because one of ordinary skill in the art can readily determine whether a given compound would fall within a claimed generic formula, the present claims fully satisfy 35 U.S.C. §112, second paragraph. Furthermore, claim 9 has been amended, and no longer recites "one or more," with the understanding that the claimed cytokine, lymphokine, growth factor, or other hematopoietic factor can be administered alone or in any combination. Accordingly, it is submitted that this rejection under 35 U.S.C. §112 should be withdrawn.

Fifth, claim 19 stands rejected under 35 U.S.C. §119, second paragraph, for differing in scope from claim 1. Applicants respectfully traverse this rejection. In particular, claims 1 and 19 are both independent claims, and properly can differ in scope. Also, claim 1 recites a method and claim 19 recites compounds. As such, claims 1 and 19 are different classes of invention, and a difference in scope of the

compounds recited in the compound and method claims is proper, if not typical. Further, both claims 1 and 19 recite "solvates." Accordingly, it is submitted that this rejection of claim 19 under 35 U.S.C. §112, second paragraph, should be withdrawn.

Sixth, claim 8 stand rejected under 35 U.S.C. §112, second paragraph, because of the recitation of "treatment of a medical condition by chemotherapeutic or radiotherapeutic" means is "silent about the condition(s), and specific radiotherapy as well as the specific chemotherapeutic treatment, [and] does not exactly say what is excluded." Applicants respectfully traverse this rejection. It is submitted that claim 8 is proper as presented, and that no requirement exists from a claim to "exactly say what is excluded," or that a claim be limited with additional recitations of specific conditions, or radiotherapies or chemotherapies.

Claim 8 recites:

"A method of sensitizing cells in an individual undergoing chemotherapy or radiotherapy for a medical condition, comprising administering a therapeutically effective amount of a compound of formula (I) in combination with a chemotherapeutic agent, a radiotherapeutic agent, or a mixture thereof to the individual. . . ."

Claim 8, therefore, recites the objective of the claimed method, namely, sensitizing cells an individual undergoing chemotherapy or radiotherapy for a medical condition. The claim also recites a step to be taken in the method, namely, administering a therapeu-

tically effective amount of a compound of formula (I) in combination with a chemotherapeutic agent, a radiotherapeutic agent, or a mixture thereof to the individual. The specification clearly discloses numerous chemotherapeutic agents and radiotherapeutic agents, and chemotherapeutic and radiotherapeutic agents are recited in dependent claims 14 and 15. In addition, persons skilled in the art are well aware of the identity of these and additional anticancer agents. Accordingly, applicants respectfully submit that claim 8 fully complies with 35 U.S.C. §112, second paragraph, and that this rejection of claim 8 should be withdrawn.

Seventh, claim 14 stands rejected because of a recitation of chemotherapeutic agents, but a failure to state what is excluded from such recited chemotherapeutic agents. For the reasons set forth above, it is submitted that this rejection is in error and should be withdrawn. It is not applicants duty to describe what is excluded from the claims, but to clearly and particularly claim applicants' invention. It is submitted that the claims adequately and particularly recite the claimed subject matter, and that the specification provides sufficient guidance as to the metes and bounds of the claims. Accordingly, it is submitted that claim 14 fully complies with 35 U.S.C. §112, second paragraph, and that this rejection should be withdrawn.

In summary, it is submitted that in view of the amendments to the claims, and for the reasons set forth above, pending claims 19, 21-25, and 28-31 are in a condition for allowance.

The examiner has objected to claims 26 and 27 as being substantial duplicates of claims 1 and 8. Applicants respectfully traverse this rejection. In particular, the scope of the compounds recited in claim 19 is different from scope of the compounds recited in claim 1. Consequently, corresponding method claims also are of different scope, and are not substantial duplicates. Applicants, therefore, submit that this provisional objection is improper, and should be withdrawn.

Claims 1-18, 26, and 27 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The examiner contends that the specification is enabling for treating rheumatoid arthritis, but not for treating cancer and other inflammatory conditions. Applicants respectfully traverse this rejection.

First, claims 1-3, 5, and 26 are directed to inhibiting checkpoint kinase 1 (Chk1) in a cell. Applicants fully and clearly teach that the claimed compounds perform this intended function at Examples 15-17 at pages 184-189 of the specification. Accordingly, it is submitted that pending claims 1-3, 5, and 26 are fully enabled by the present invention.

Second, claims 8-12, 14-18, and 27 are directed to administering a claimed Chk1 inhibitor to sensitize cells in an individual undergoing chemotherapeutic or radiotherapeutic treatment for a medical condition. It must be pointed out that the claimed Chk1 inhibitors are *not* used *alone* to treat a cancer or other inflammatory conditions, but are used as an

adjunct to a chemotherapeutic or radiotherapeutic treatment.

In practice, a physician diagnoses a cancer in an individual, and prescribes the proper treatment, either chemotherapeutic, radiotherapeutic, or both, to treat the cancer. In addition to this prescribed treatment, a compound of the present invention can be administered to the individual to sensitize cells to the prescribed treatment, and thereby render the treatment more effective.

A present Chk1 inhibitor is not administered alone to treat a cancer, and if administered alone does not treat a cancer. A primary cancer treatment is required. This is clearly set forth in claims 8-12, 14-18, and 27, each of which requires coadministration of a chemotherapeutic agent, radiotherapeutic agent, or both.

Accordingly, the administration of a claimed Chk1 is independent of the cancer or prescribed treatment. The present compounds are not a "silver bullet" as contended by the examiner, but sensitize cells to treatment with the prescribed method for the diagnosed cancer, regardless of the cause or etiology of the cancer, or the body tissue afflicted by the cancer.

In addition, all method claims 8-12, 14-18, and 27 recite that the individual is being treated with a chemotherapeutic and/or radiotherapeutic agent. The individual may be suffering from any one of a variety of diseases, including inflammatory diseases, treatable with ionizing radiation (see specification, page 37, line 14 through page 38, line 2). In each case, the

use of a present Chk1 inhibitor *is in combination* with the primary chemotherapeutic and/or radiotherapeutic agent in order to sensitize cells to these agents.

In addition, persons skilled in the art are well aware of the identity of prodrugs, solvates, and pharmaceutical salts. The point of attachment and identity of salts is apparent from the acidic or basic centers present in the compound, and pharmaceutically acceptable salts are well known to persons skilled in the art (see, for example, specification at page 39, line 17 through page 40, line 3). A solvate or hydrate is readily determined from the identity of the solvent from which the compound is precipitated or crystallized, i.e., a solvate is a hydrate when the solvent is water. Persons skilled in the art also are aware of which groups on a compound are capable of being functionalized to form a prodrug, and which compounds can be used as functionalizing agents to provide a prodrug. Also, solvates and hydrates do not alter the structure of the compound, a salt of the compound is readily transformed to the compound at the proper pH, and prodrugs of the compound are readily converted to the compounds by *in vivo* conditions known to persons skilled in the art after considering the route of administration of the prodrug.

Accordingly, for the reasons set forth above, it is submitted that claims 1-3, 5, 8-12, 14-18, 26, and 27 fully comply with 35 U.S.C. §112, first paragraph. In summary, it is submitted that all pending claims are now in a condition for allowance. An early

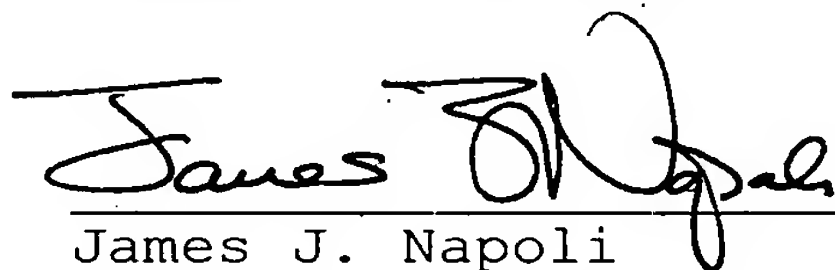
and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Respectfully submitted,

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By

A handwritten signature in dark ink, appearing to read "James J. Napoli", is written over a horizontal line.

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